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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,891	07/06/2000	James McArthur	40567	6712

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/610,891	Applicant(s) MCARTHUR ET AL.	
	Examiner MISOOK YU, Ph.D.	Art Unit 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *35-40 and 44-47*.

   Claim(s) withdrawn from consideration: *48-59*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

LARRY R. HELMS, PH.D.
PRIMARY EXAMINER

Misook Yu, 1/25/05

Continuation of 2. NOTE: The amendment to claim 35 does not make much very sense. It is not clear whether the new limitation "elicits" in line 4 of claim 35 is typographical error or has some other meaning to the composition being claimed.

Continuation of 5. does NOT place the application in condition for allowance because: even if the after-final amendment were entered, claims 35-40, 44-47 would remain rejected for ~~reasons~~ reasons of record.

In response to applicant's argument that Sanda et al., is directed to an animal model, and lacks teaching or suggestion for generating a humoral immune response to a human prostate tumor-associated antigen having the recited molecular weights, and Savarese et al., and Thomas et al., that teach GM-CSF expressing LnCap, PC3, or DU145 do not compensate for the lack of the teaching of Sanda et al., the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the primary reference (Sanda teaches that vaccine composition comprising irradiated prostate cancer cells (i.e. proliferation-incompetent) genetically engineered to secrete human granulocyte-macrophage colony-stimulating factor (GM-CSF) is effective for treating anaplastic, hormone refractory prostate cancer. The primary reference does not teach LnCap, PC3, or DU145.
However, the secondary reference (Savarese et al.) teach that LnCap, PC3, or DU145 are well known prostate cell lines and also teach how to culture those cells at page 81. Neither the primary reference nor the secondary reference teaches why one of skill in the art would be motivated to make and use irradiated (i.e. proliferation-incompetent) prostate established cell line cancer cells genetically engineered to secrete human granulocyte-macrophage colony-stimulating factor (GM-CSF).

However, the tertiary reference (Thomas et al.) teach that whole tumor cell vaccines engineered to secrete certain GM-CSF induce potent systemic immune responses and expanding primary autologous human tumor cells have been used in clinical trials but have been found impractical due to the technical difficulty of routinely expanding primary autologous human tumor cells to the numbers required for vaccination, making the generalization of autologous vaccines impractical. GM-CSF-transduced allogeneic vaccines induce systemic antitumor immunity, and suggests allogeneic whole tumor cell vaccine approach might be a good idea.

Therefore, it would have been obvious to make and use composition comprising proliferation-incompetent LnCap, PC3, or DU145 cells engineered to express GM-CSF with a reasonable expectation of success given that LnCap, PC3, or DU145 cells could be obtained from a commercial vendor as taught by the secondary reference and making a proliferation-incompetent cells or genetic engineering to secrete human granulocyte-macrophage colony-stimulating factor (GM-CSF) had been known well before the effective filing date of the instant application as taught by the primary reference. One of ordinary skill in the art would have been motivated to make and use the instantly claimed invention, given that using already established cells are more practical than expanding primary cells as taught by the tertiary reference, and allogeneic vaccine also works.

As for arguing with the limitation a prostate tumor-associated antigens of 250, 160, 150, 31 kD, 26 kD, or 14 kD, these antigens are not part of the claimed composition. Rather administering GM-CSF expressing LnCAP, PC3, and/or DU145 induces those antigens. Therefore GM-CSF expressing LnCAP, PC3, and/or DU145 are the active ingredients, and all the rest is either intended use or a result of administration of the composition.

LARRY R. HELMS, PH.D
PRIMARY EXAMINER